ENCISION
DELIVERING ENERGY SAFELY

JUN 16 2014

510(k) Summary

Device	**EndoShield Burn Protection System**
Owner	Encision, Inc.
Contact	Mike Biggs, Director Engineering and Interim Director RA/QA
Date	11 June 2014

Subject Device

Trade name	**EndoShield Burn Protection System**
Model number	**EM100**
Common name	**Disposable AEM Monitor**
Device name	**Electrosurgical, Cutting & Coagulation & Accessories**
Regulation number	**21 CFR 878.4400**
Product code	**GEI**
Device class	**2**
Panel	**General and Plastic Surgery**

Predicate Device

Trade name	**EM3 AEM Monitor**
Device name	**Electrosurgical, Cutting & Coagulation & Accessories**
Manufacturer	**Encision Inc.**
Market clearance	**510(k): K122383 (2013)**

Device Description

Device purpose

- Enables AEM Monitoring and protection during monopolar laparoscopy
- Transfers high-frequency (HF) energy from monopolar electrosurgical unit (ESU) to AEM laparoscopic instruments while providing AEM Monitoring of HF current returning from the instrument's shield
- Disables HF energy delivery and presents a visual alert whenever a set up or operational fault is detected

AEM technology

- Safety system for minimally-invasive monopolar electrosurgery
- Prevents unanticipated or undetected burns from stray HF energy outside the surgeon's field of view
- Works by shielding instrument's shaft from stray HF energy due to insulation breakdown or capacitive coupling
- Monitors level of energy picked up by shield; interrupting energy delivery when energy in shield approaches excessive levels

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Device Description (continued)

Device components	EndoShield is a self-contained battery-powered electronic module (about the size of a cell phone) with integral instrument and HF power cords: • Module plugs directly into return-electrode receptacle of ESU • Integral cords connect module to – AEM laparoscopic instrument – Foot-control power output receptacle of ESU

Technological Characteristics

EndoShield miniaturizes and integrates the primary monopolar functions of the predicate device, EM3 AEM monitor, into a single-use, self-contained system.

Technology

Logic	• Battery-powered digital and analog electronic circuitry • 3V Lithium battery • Normally-open relay controlling primary HF energy path • DSP HF current measurement of shield-to-ground HF energy • Shield HF threshold detection results in opening of relay of primary HF path and lighting of red visual indicator
Instrument connector	Dual, gold plated, spring loaded, connector allowing free rotation of connector on instrument post at end of instrument cord
ESU return connector	Standard CQM-type return electrode three-pin plug on back of monitor module
ESU HF output connector	Standard ESU foot-control instrument plug on short cord from module
Visual indicator	• Green light-emitting diode lighting a ready light: a "✓" molded into the electronic module housing • Red light-emitting diode lighting an alarm/not-ready light: an "X" molded into the electronic module housing

Function	
Enables energy delivery	Assures all connections are proper before enabling energy delivery and presenting a visual "ready" indication by lighting a green "✓" on face of electronic module
Shields from stray energy	Monitor connections shunt stray energy, attempting to pass through the insulated shaft of an AEM instrument by insulation breakdown or capacitive coupling, back to the ESU
Disables energy delivery	Monitor shuts down the electrosurgical procedure if the level of stray energy reaches dangerous levels
Indicates fault	Visual alert—extinguishes green "✓" and lights red "X" on face of electronic module—indicates a fault is detected, either at set up (system not ready) or during operation (excess stray energy)

Intended Use

The EndoShield Burn Protection System is an accessory for use with electrosurgical generators and electrodes that is designed to safely deliver electrosurgical energy and to prevent injury caused by insulation failure and capacitive coupling.

EndoShield performs active electrode monitoring intended to control stray monopolar energy, caused by insulation failure and capacitive coupling in surgical instruments, along the shaft of the instrument.

Equivalence

Based on operating principle, intended use, technology, safety, and performance; the EndoShield Burn Protection System is substantially equivalent to its predicate device, the monopolar function of the EM3 AEM Monitor.

	EndoShield equivalence to EM3 (Monopolar function)
Intended Use	Identical intended use as an accessory for use with electrosurgical generators and electrodes to safely deliver electrosurgical energy and to prevent injury caused by insulation failure and capacitive coupling through active electrode monitoring.
Operating principle	Identical operating principle: shunting stray energy from the shield of an AEM Instrument to ESU return-electrode ground and disabling energy delivery should stray-energy current exceed a predetermined threshold.

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Equivalence (continued)

	EndoShield equivalence to EM3 (Monopolar function)
Materials	Substantially equivalent materials: typical electrical wires, connectors, analog and logic components, and printed circuit boards; primary differences are battery instead of mains power and plastic instead of metal enclosure.
Technology	Substantially equivalent circuitry: discrete digital logic, analog electronics, and HF power relays instead of FPGA logic device (with software), analog electronics, and HF power relays
Performance	Substantially equivalent: specifications are equivalent, except for the alarm display being visual only and not specific to the type of fault detected
EMC and Electrical Safety	Identical standards and internal design control assurances, including recognized international standards: • IEC 60601-1 (3rd Ed.) compliant • IEC 60601-1-2 compliance • IEC 60601-2-2 compliance
Human factors/ usability	Identical standards and internal design control assurances, including recognized international standards: • IEC 60601-1-6 compliance • IEC 62366 compliance

Bench Testing

Essential performance testing	In accordance with Design Control requirements per 21 CFR 820.30, essential performance tested in 10 units showed equivalent performance to monopolar function of EM3 AEM Monitor predicate system.
EMC, electrical safety, usability	Third-party testing and design-file review demonstrated equivalent performance to monopolar function of EM3 AEM Monitor predicate system.

Biocompatibility

Patient Contact	No direct or indirect contact with patient
Biocompatibility Evaluation	None required

Sterility / Packaging

Sterility	• Method of sterilization: ethylene oxide gas • Methodology: ANSI-AAMI-ISO 11135-1:2007 • Sterility assurance level: 10^{-6} or better • Sterilization performance: By a qualified contract sterilizer
Sterility Maintenance/ Shelf Life	• Initially, product validated for sterility and function to one year shelf life • Assurance method: accelerated aging • Validated shelf life indication: "use by" date on all labels—boxes and pouches • Post-market extension of shelf life: life extended as data from accelerated and real-time aging tests demonstrate greater longevity

Conclusion

EndoShield Burn Protection System is substantially equivalent to the monopolar function of its predicate devices in performance and intended use. There are no significant differences between EndoShield Burn Protection System and the EM3 predicate in design which would raise new issues of safety and effectiveness, performance, function or intended use of the device. Technological similarities between the predicate device and the proposed device also demonstrate equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 16, 2014

Encision Incorporated
Mr. Mike Biggs
Vice President, Regulatory and Quality
6797 Winchester Circle
Boulder, Colorado 80301

Re: K140006
Trade/Device Name: EndoShield Burn Protection System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical, Cutting & Coagulation & Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 14, 2014
Received: May 15, 2014

Dear Mr. Biggs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140006

Device Name
EndoShield Burn Protection System

Indications for Use *(Describe)*
The EndoShield Burn Protection System is an accessory for use with electrosurgical generators and electrodes that is designed to safely deliver electrosurgical energy and to prevent injury caused by insulation failure and capacitive coupling. EndoShield performs active electrode monitoring intended to control stray monopolar energy, caused by insulation failure and capacitive coupling in surgical instruments, along the shaft of the instrument.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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